

HALO^{FLEX} Generator

Model 1190A-115A, 1190A-230A

TECHNICAL MANUAL

BÂRRX Medical, Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085
USA

Telephone: (888) 662-2779

Facsimile: (408) 738-1791

Support: support@barrx.com

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1.0 SCOPE

This Technical Manual for the BÂRRX HALO^{FLEX} Energy Generator contains the technical description, instructions for use and BÂRRX Medical contact information.

2.0 REFERENCE DOCUMENTS

- 1190A-115A: HALO^{FLEX} Energy Generator
- 717-0014-01 : User Manual , HALO^{FLEX} Energy Generator
- NFPA 99: Health Care Facilities Code

3.0 ATTACHEMENTS

- One 717-0014-01 HALO^{FLEX} Energy Generator User Manual
- One L-0146-01 BÂRRX Energy Generator Service Plan Sheet

4.0 INTRODUCTION

This Technical Manual is for the BÂRRX HALO^{FLEX} Energy which consists of

- One 1190A-xxxA HALO^{FLEX} Generator
- One FLEXCC-020A: HALO^{FLEX} Output Cable
- One FLEX FS-010A: HALO^{FLEX} Footswitch
- One 90-9030: Hospital Grade Power Cord
- One 717-0014-01: HALO^{FLEX} Generator User Manual

The HALO^{FLEX} Energy Generator supplies up to 300 watts of radiofrequency (RF) power at 460 kHz in a bipolar mode under power control while continuously monitoring and displaying power, energy density, and balloon inflation pressure. See user manual 717-0014-01 for additional details. This User's Manual provides a description of the Energy Generator, Output Cable, Disposable Devices, Footswitch, the Energy Generator's controls and displays, and a sequence for its operation.

5.0 CONTRAINDICATIONS

This Technical Manual should be used in conjunction with the 717-0014-01 HALO^{FLEX} Generator Instructions.

6.0 WARNINGS / PRECAUTIONS

- All service must be performed by an Authorized Repair Facility. All service or repair questions should be directed to the BÂRRX Medical Customer Service Department. Because the repair of electrosurgical generators requires specialized knowledge and equipment, there are no user serviceable parts within the energy generator. **Opening the energy generator enclosure voids all warranties.**
- See User Manual 717-0014-01 for additional Warnings and Precautions.

7.0 UNPACKING AND INSPECTION

The BARRX Energy Generator is packaged in approved BARRX Medical packaging materials for protection during transit. The main packaging contains the accessory box which contains the Generator accessories, and the Generator in plastic bag with desiccant and protective end caps.



Shipping Box



Accessory Box



Generator

7.1 UNPACKAGING / INSPECTION

7.1.1 Remove Generator and accessories from packaging.

7.1.2 Verify Contents

- For Model 1190A-115A BARRX HALO^{FLEX} 115V Energy Generator
 - One 1190A-115A BARRX HALO^{FLEX} Energy Generator.
 - One FLEXCC-020A HALO^{FLEX} Output Cable
 - One FLEXFS-010A HALO^{FLEX} Footswitch
 - One 717-0014-01 HALO^{FLEX} User Manual
 - One 90-9030 Hospital Grade Power Cord
- For Model 1190A-230A BARRX HALO^{FLEX} 230V Energy Generator
 - One 1190A-230A BARRX HALO^{FLEX} Energy Generator.
 - One FLEXCC-020A HALO^{FLEX} Output Cable
 - One FLEXFS-010A HALO^{FLEX} Footswitch
 - One 717-0014-01 HALO^{FLEX} User Manual
 - One 90-9030 Hospital Grade Power Cord

7.1.3 Verify no visible damage to Generator or accessories.

7.2 INSTALLATION / TESTING

7.2.1 Verify Output Cable connects easily to Generator front RF output connector.

7.2.2 Verify Footswitch connects easily to Generator rear footswitch connector.

7.2.3 Use supplied power cord to plug Generator into approved power outlet.

7.2.4 Power ON Generator, verify Generator Passes its Power On Self Test.

7.3 ADJUSTMENTS AND ALIGNMENTS

7.3.1 No adjustments, alignments or calibrations required.

8.0 INSTALLATION, ADJUSTMENTS AND ALIGNMENTS

8.1 No adjustments, alignments or calibrations required.

8.2 Refer to 717-0014-01 User Manual HALO^{FLEX} Energy Generator for Installation.

9.0 LOCATION / FUNCTION OF CONTROLS

Refer to 717-0014-01 User Manual HALO^{FLEX} Energy Generator Installation section.

10.0 CONNECTION TO PATIENT

Refer to 717-0014-01 User Manual HALO^{FLEX} Energy Generator.

11.0 TESTING GENERATOR

11.1 HALO^{FLEX} Energy Generators are subject to 100% testing at manufacturer prior to shipment. The final product release testing is comprised of the following product performance evaluations:

- Burn-in / RF Power Cycling
- Software and Real Time Clock Check
- Output Cable Resistance and Leak Testing
- Waveform Quality and Frequency Check
- RF Output Calibration Check
- Footswitch and Front Panel Control Check
- Pressure and Leak Testing
- HIPOT Testing: AC Cord
- HIPOT Testing: Output cable
- Safety Leakage Current Testing to Generator
- Power Cycling / Power On Self Test Check

Final test report for system is available upon request.

11.2 POWER ON SELF TEST

The BARRX Medical HALO^{FLEX} Energy Generator performs a series of self-tests each time the unit is powered up. Tests included in this self check are a power output test, voltage output test and a current output test (see table 1 for details). If any of these respective tests fail to meet their specification as noted in Table 1, while booting up, the generator will display an error message and not allow the user to continue without re-booting the system. The LCD display and user manual will instruct the user on how to proceed.

Refer to 717-0014-01 User Manual HALO^{FLEX} Energy Generator POST (Self-Test Mode section for additional details

11.3 ADDITIONAL TESTING

BARRX Medical does not recommend any additional 'output' testing on this generator at the customer site due to the unique operation conditions of the system and most importantly because of its inherent 'self-test' algorithms. The unique operational conditions used to run this generator require that testing be conducted for up to 20amps of current, on a high frequency 1.0 ohm load with the aid of an oscilloscope to catch the 'on time' which is usually less than 0.3sec. Testing by the customer outside of this operational range could generate erroneous information, damage the generator and/or void the warranty.

Table 1. POWR ON SELF TEST ERROR CODES

P01	POST CPU Configuration Error	Disconnect Catheter P01- Cycle Power	Configuration Register Test verification
P02	POST ROM Test Error	Disconnect Catheter P02- Cycle Power	CRC test verification
P03	POST RAM Test Error	Disconnect Catheter P03- Cycle Power	RAM Test verification
P04	POST Power Error	Disconnect Catheter P04- Cycle Power	Verify POST Power
P05	POST Impedance Error	Disconnect Catheter P05- Cycle Power	Verify POST Impedance
P06	POST Voltage Error	Disconnect Catheter P06- Cycle Power	Verify POST Voltage
P07	POST Current Error	Disconnect Catheter P07- Cycle Power	Verify POST Current
P08	POST Reference Voltage Error	Disconnect Catheter P08- Cycle Power	Verify Reference Voltage
P09	POST Watchdog Test Error	Disconnect Catheter P09- Cycle Power	Verify watchdog timer
P10	POST Output Transformer Impedance Error	Disconnect Catheter P10- Cycle Power	Verify Output Transformer Impedance
P11	POST Pressure Sensor Offset Error	Disconnect Catheter P11- Cycle Power	Verify ambient pressure sensors
P12	POST Pressure Reference Voltage Error	Disconnect Catheter P12- Cycle Power	Verify pressure sensor reference voltage.
P15	POST Real Time Clock Test Error	Disconnect Catheter P15- Cycle Power	Read and verify the RTC Test Pattern
P16	POST Real Time Clock Date Error	Disconnect Catheter P16- Cycle Power	Verify real time clock
P17	POST Switch Closed Error	Disconnect Catheter P17- Cycle Power	Verify no switches are shorted

12.0 PROPER USE OF GENERATOR

Refer to 717-0014-01 User Manual HALO^{FLEX} Energy Generator

13.0 SAFETY CONSIDERATIONS

Refer to 717-0014-01 User Manual HALO^{FLEX} Energy Generator

14.0 SYSTEM DIAGRAMS

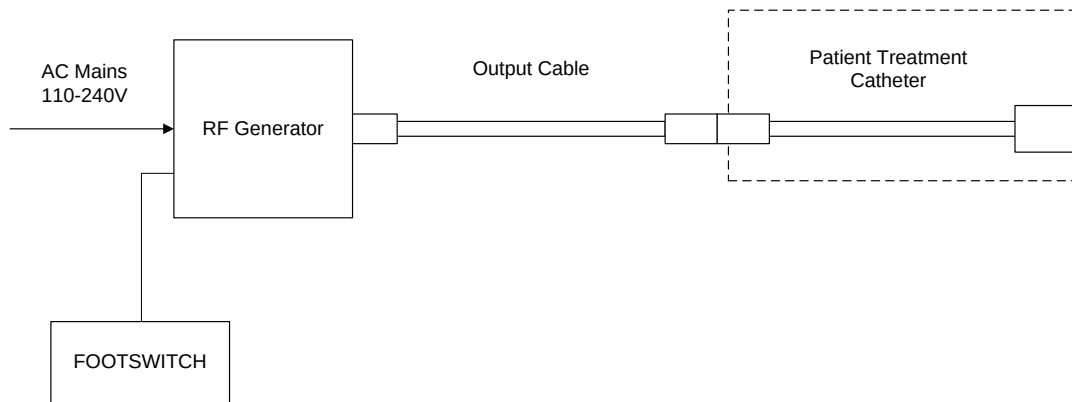


Figure 1 Major Component Diagram for the BÂRRX HALO^{FLEX} Energy Generator System

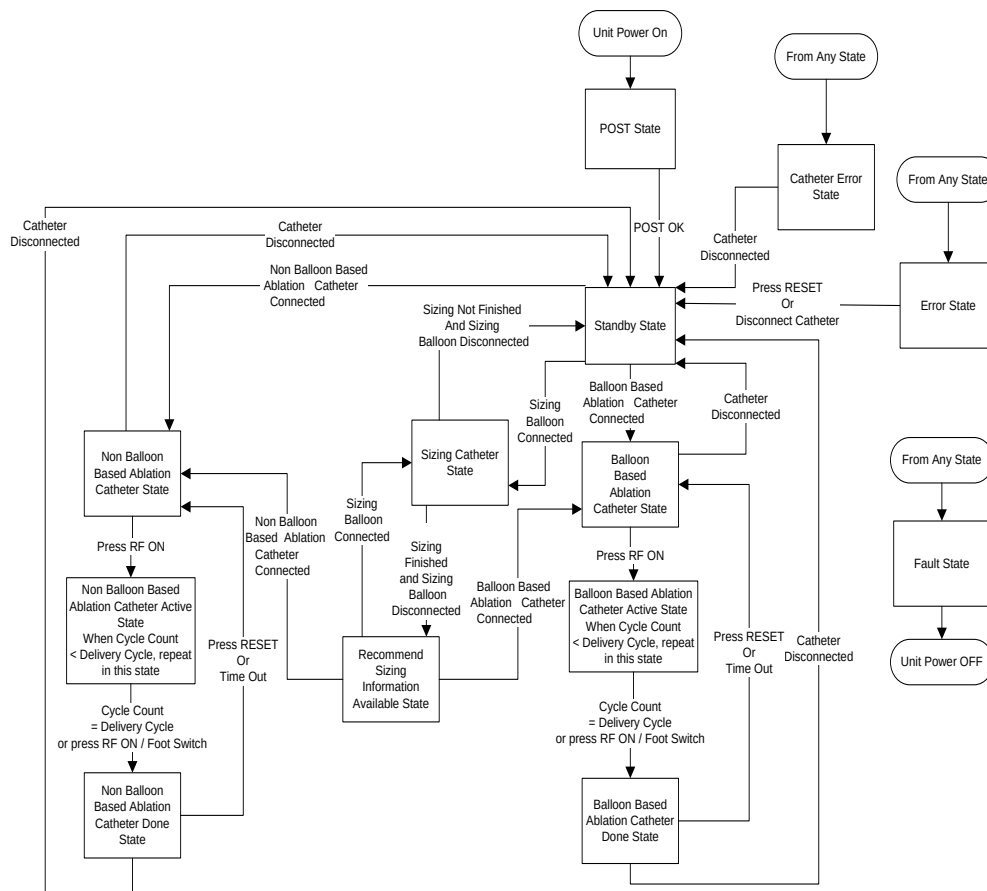


Figure 2: System State Diagram

15.0 ENERGY GENERATOR CLEANING AND DISINFECTION INSTRUCTIONS

Use a mild detergent and damp cloth to clean the Energy Generator cover, front panel, and power cable. The Energy Generator is not sterilizable. Do not allow fluids to enter the Energy Generator chassis. The Energy Generator may be disinfected using a standard hospital alcohol solution applied with a cloth or by wiping down equipment with sodium hypochlorite 500 ppm wipes; leaving it in contact with all surfaces for 10min; then using a

damp cloth clean with neutral detergent. Do not expose the metal pins of the connector to the sodium hypochlorite wipes in order to prevent corrosion. Do not spray or pour liquids directly on the unit.

16.0 UTILITY SUPPLY REQUIREMENTS

Plug the Energy Generator into a grounded hospital grade power outlet (extension cords and/or adapter plugs must not be used).

17.0 FIGURES, SYMBOLS AND ABBREVIATIONS ON GENERATOR

Refer to 717-0014-01 User Manual HALO^{FLEX} Energy Generator

18.0 TECHNICAL PERFORMANCE SPECIFICATIONS

Refer to 717-0014-01 User Manual HALO^{FLEX} Energy Generator

19.0 PREVENTATIVE AND CORRECTIVE MAINTENANCE AND REPAIR PROCEDURES

19.1 No Calibration is required

19.2 The HALO^{FLEX} Generator has no user serviceable parts

19.3 Preventative Maintenance:

- User should periodically
 - Verify Generator functionality by powering ON the Generator and verify the Generator passes its self-test function. (See Testing section of this manual)
 - Verify power cord is not frayed or damaged
 - Verify no visible damage to Output Cable or Footswitch.

19.3 Troubleshooting

Refer to 717-0014-01 User Manual HALO^{FLEX} Energy Generator Troubleshooting section.

20.0 SERVICE AND SUPPORT

- For Additional Information / Technical Support, email BÂRRX Medical Service Dept at support@barrx.com or contact BÂRRX Medical Customer Service Toll Free at 1.888.66-BARRX (1.888.662.2779)

Note: This product is UL listed and to satisfy UL requirements BARRX Medical is subjected to quarterly UL audits where a UL representative verifies that the current production meets the UL mark requirements and that the product adheres to the critical component lists derived as result of UL construction and engineering analysis.